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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,986	05/07/1999	THUAN QUOC TRINH	IVGN 202	4261

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
11/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/306,986	TRINH ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13,56 and 70-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13,56 and 70-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 8 and 56, in the paper of 7/9/2009 is acknowledged.

Claims 8-13, 56 and 70-75 remain at issue and are present for examination. Applicant's review of the case history of the present application is also acknowledged and appreciated. Applicants' arguments filed on 7/9/2009, have been fully considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is noted that applicants amendment of the claims in the paper of 7/9/2009, is not compliant with 37 CFR 1.121 with regard to the showing of that which is added to claims, by underlining, and that which is deleted from the claims by double bracketing or strike through. For instance claim 8 has numerous changes that are not properly indicated as being a change (i.e. double bracketing or strike through to indicate deleted subject matter). Given the complexity of applicant's claims this makes prosecution of applicants claimed invention extremely difficult. Applicants are put on notice to pay special attention to applicant's amendments in future correspondence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 8-13, 56, 70-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Major (Biotechniques 12:40-43, 1992) as evidenced by Deana and Belasco (Mol. Microbiology, Vol. 51, No. 4, pp 1205-1217, 2004) and O'Donnell (Journal of Biological Chemistry, Vol 262, No. 34, pp 16558-16565, 1987) is hereby withdrawn based upon applicants amendment of the claims and applicants argument that Major does not teach adding a ribonucleoase to said crude preparation.

Claims 8-13, 56, 70-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Maudru et al. (Journal of Virological Methods 66: 247-261, July 1997).

As previously stated, Maudru discloses the method of the claimed invention at page 250, beginning in the bottom of column 1 in the section entitled "2.2.2. *Polymerase chain reaction (PCR)".* This section describes conduction of PCR in the presence of both RNase and thermostable DNA polymerase. Thus Maudru describes a step of "a) mixing the preparation with one or more DNA polymerases, and one or more peptides or polypeptides having ribonuclease activity, wherein said peptides or polypeptides having ribonuclease activity are capable of degrading single-stranded RNA," as claimed. The preparation of Maudru et al. is considered a crude preparation as applicant's specification states that: "The composition is especially useful in DNA synthesis when the sample is crude, i.e. prepared rapidly such that it contains contaminating RNA". Because Maudru conducts PCR using a double stranded DNA, Maudru discloses a step of "b) incubating said mixture under conditions sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-

stranded DNA and under which said peptides or polypeptides having ribonuclease activity degrade said single-stranded RNA," as claimed. Maudru section 2.2.2. further describes conducting RNAse digestion for 30 minutes prior to conducting PCR for 35 cycles and the inclusion of buffers and nucleotides. This procedure is conducted to reduce background signals caused by an intrinsic RNA-dependent DNA polymerase activity of the thermostable Taq DNA polymerase, the enzyme used in PCR. (Maudru, abstract.). It is noted that while Maudru et al. do not necessarily teach that said methods include a detectably labeled nucleotide, claim 13 is drawn to the method of claim 10 which is drawn to the inclusion of such detectably labeled nucleotide in the alternative. Further claims 70-75 are included in the rejection because claims 70-75 appear to specify the "conditions sufficient to synthesize " a specific type of double stranded DNA. As the "conditions sufficient to synthesize " taught by Maudru et al. are sufficient to synthesize each of the various double stranded DNAs recited in claims 70-75, these claims are included in the rejection.

Applicants traverse this rejection on the basis that Maudru et al. does not disclose the step of adding one or more DNA polymerases and one or more peptides or polypeptides having ribonuclease activity to a nucleic acid preparation comprising RNA and double-stranded DNA. Applicants submit that instead, Maudru et al. teaches adding RNase and DNA polymerase to the products of RT reactions *(i.e.,* reactions comprising cDNA). Applicants submit that the resultant single-stranded cDNA of Maudru et al.'s RT "preparations" requires further conversion by DNA polymerase before becoming double stranded DNA.

Applicants amendment of the claims and applicants complete argument are acknowledged, however, not found persuasive for the reasons previously stated and for those reasons stated herein. Maudru et al. clearly describes conduction of PCR in the presence of both RNase and thermostable DNA polymerase, which includes the adding to said crude preparation of RT reaction, one or more DNA polymerases and one or more polypeptides having ribonuclease activity, wherein said polypeptide having ribonuclease activity is capable of degrading single stranded RNA. The RT reactions to which the DNA polymerase and ribonuclease polypeptides of Maudru et al. were added were generated using AMV RT as well as M-MLV RT, which are each know to generate a DNA product from template DNA, RNA or RNA:DNA hybrids. One of skill in the art would appreciate that while the purpose of a RT reaction is to generate a cDNA copy of RNA, thus creating a RNA:DNA hybrid, such reactions will additionally generate double stranded DNA products due to degradation of the RNA portion of the RNA:DNA hybrid molecule followed by subsequent second strand synthesis as well as the generation of second strand synthesis as a result of the random initiation events as a result of polydT priming at poly-A tracts of DNA. Thus the RT-reaction products to which Maudru et al. teach the addition of DNA polymerase and ribonuclease contained both RNA and double-stranded DNA.

Thus Maudru continues to anticipate claims 8-13, 56, 70-75.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgh
10/28/2009

/Richard G Hutson/
Primary Examiner, Art Unit 1652